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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Assessment of Preclinical Reproductive Toxicity Data; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting to discuss an approach for the integrative assessment of preclinical reproductive toxicity findings and other information for pharmaceuticals. The purpose of the meeting is to provide information on the agency's approach, using several pharmaceutical data sets, and to invite members of the public to provide comments on the utility of the approach. The agency intends to consider feedback from the meeting in the development of guidance for integrative assessments of pharmaceutical reproductive risk.

**DATES:** The public meeting will be held on June 24, 1999, from 9 a.m. to 4 p.m. Submit registration information by June 11, 1999.

**ADDRESSES:** The public meeting will be held in the Center for Drug Evaluation and Research Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Adele S. Seifried, Center for Drug Evaluation and Research (HFD-024), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5482.

#### SUPPLEMENTARY INFORMATION:

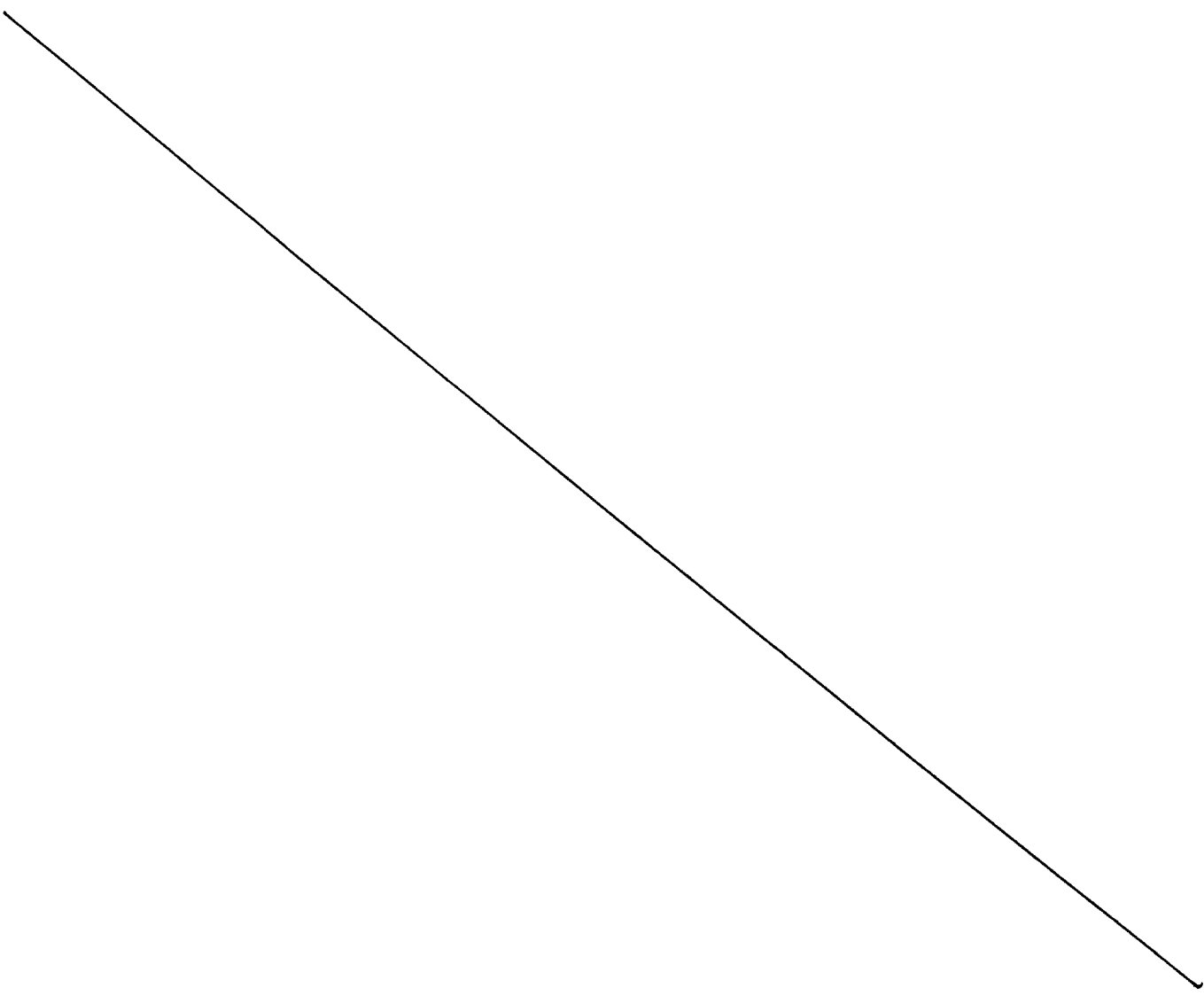
*Registration.* Although there is no fee, preregistration by June 11, 1999, is required for all attendees at this meeting. Participation is limited to the first 75 registrants outside FDA and is also restricted within FDA due to limited meeting space. Persons interested in attending the meeting should register via e-mail to "wedge@cder.fda.gov" using the registration form on the Center  
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for Drug Evaluation and Research home page “<http://www.fda.gov/cder>” or, if e-mail is not available, fax their registration information (including name, affiliation, address, telephone, fax number, and e-mail address) to 301–827–6801, ATTN: Kimberly L. Topper. Interested persons may also register by mailing the registration information to the contact person identified previously.

*Building Location and Admittance.* The building at 5630 Fishers Lane is the former Social Services Building located next to the Parklawn Building. Please use the lower entrance, which faces Parklawn Dr. Visitor badges for nonagency participants will be held at the guard station at the entrance to the building. Participants will need picture identification to pick up their badge.

*Parking.* There is no public parking at the building at 5630 Fishers Lane. A public parking lot (for a fee) is located on Fishers Lane across from the Parklawn building, and additional public parking (for a fee) is available at the Twinbrook Metro station located several blocks to the west.



*Agenda.* An agenda for the public meeting will be available 2 weeks before the meeting, via the Internet using the World Wide Web (WWW). Connect to the CDER home page at “<http://www.fda.gov/cder>” and go to the “What’s Happening” section.

Dated: April 28, 1999



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William K. Hubbard  
Associate Commissioner for Policy Coordination

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